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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/080,502 | 02/22/2002 | Jeffrey L. Cleland | 146392000500 | 8669 |

25226 7590 03/23/2009
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| EXAMINER |
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AZPURU, CARLOS A

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| ART UNIT | PAPER NUMBER |
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1615

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| MAIL DATE | DELIVERY MODE |
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03/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/080,502 | Applicant(s) CLELAND ET AL. | |
| | Examiner Carlos A. Azpuru | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 6, 9-11, 14, 16, 19, 20-22, 44, 48, 55-58, 60-63, 66-73, 75-81, 84-88 is/are rejected.
- 7) ☒ Claim(s) 4, 15, 55, 64, 82 and 83 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10162008 & 10302009</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1, 4,5,6,9-11, 14-16, 19, 20-22, 44, 48, 56-58, 60- 64, 66-73, 75-81, 82-88 .

DETAILED ACTION

Receipt is acknowledged of the amendment filed 01/09/2009. Information disclosure statements were filed on 10/16/2008 and 10/31/2009.

The following rejection is maintained in this action:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5,6,9-11, 14, 16, 19, 20-22, 44, 48, 55-58, 60- 63, 66-73, 75-81, 84-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over PCT/US97/23659 (Brodeck et al).

Brodeck et al disclose a viscous gel vehicle comprising a biocompatible polymer, a mixture of solvents and a bioactive (see Abstract; page 13, lines 1-6). The mixture itself may comprise hydrophobic and hydrophilic solvents in admixture so as to form a solvent with a water solubility of less than 1 wt % (see page 24, lines 20-210). The viscosity of the gel may be less than 1000 centipoise (see page 3, line 6). The solvent mixture is more specifically defined as a mixture of hydrophilic solvent (Which can be up to 50 wt % and a hydrophobic solvent. Benzyl benzoate is specifically recited as the hydrophobic

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solvent and can be found at concentrations of greater than 50% or 80 % (see page 28, lines 1-23). The beneficial agent can be found at a concentration of between 1 and 50% at page 4, lines 7-8. The concentration of the beneficial agent can be up to 100 mg/ml. (see page 51, lines 12 and 14). Release of the bioactive within the first 24 hrs is 20% or less (see page 2, lines 17-21). The bioactive may be dispersed or dissolved in the gel as shown at page 11, line 8, as well as throughout the specification. Viscosity of the gel is found at page 37, line 6. The particular combination of solvents, polymers and bioactives may be found at page 28, lines 1-2; page 23, lines 3-24; page 24, lines 1-5; page 41, lines 3-24; page 42, lines 1-24; page 43, lines 1-24; page 44, lines 1-24; page 45, lines 1-11. The claimed method differs only in the gauge of the needle used to administer the gel. However, adjustment of the viscosity for other methods of administration is taught at page 37, lines 13 -19. Therefore, those of ordinary skill would have found it well within their ability to adjust the pH according to whatever gauge needle was being used according to the teachings of Brodeck et al. The instant claims would have therefore been obvious to one of ordinary skill in the art at the time of invention given the teachings of Brodeck et al.

Response to Arguments

Applicant's arguments filed 01/09/2009 have been fully considered but they are not persuasive.

Applicant argues that viscosity modification only occurs by addition of emulsifying agents. However, this modification does not necessarily need to happen since the viscosity is already within the range set out by the claims.

Further, although applicant has eliminated gels as one form of the composition, the language is not closed and ultimately does not exclude it. Further, applicant's viscosity ranges are still inclusive of a range that would include a gel.

Viscosities are already disclosed as below 1000 centipoise (page 3, line 6), so there is no reason why the ordinary practitioner would not believe a 25, 28 or 30 gauge needle could not be used to administer the composition. Applicant already sets out that the viscosity of their composition is below 2000 centipoise. If the instant composition can be used with 25, 28 or 30 gauge needles, those of the reference would have no problem during administration.

As such, the rejection under 35 USC 103(a) over Brodeck et al is maintained in this action.

Claims 4,15,55,64,65,82 and 83 are objected to as dependent upon a rejected base claim.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

caz